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EXAMINER

ROSE, SHEP K

ART UNIT PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/489310	Applicant(s) STEPHENSON
Examiner S HOP ROSE	Group Art Unit 1610

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ R responsive to communication(s) filed on CPA Sept. 26 2001
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 11, 15, 17 & 20, 22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 11, 15, 17 & 20, 22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ S the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 11
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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Claims 6 and 16 to 5, 7 to 10, and 21, all method claims are canceled and claims 11 to 15 17 to 20 and 22 to "KITS" are presented and the balance of the claims amended to have the acidic polyphosphate beverage substantially free of calcium and fluoride.

A telephone interview October 18 as a follow up of the earlier interview Friday May 25, 2001 between the undersigned USPTO Examiner and applicants' counsel, Kelly McDaw-Dunham, clarified the page 8 election, with traverse, of one ultimate disclosed species of (B) beverages containing fruit juice and (C) carbohydrate sweeteners, since both are generic to plural species. All fruit juice species and all carbohydrate sweeteners are considered to be obvious variants of each other, and, accordingly, are not to be regarded as patentably distinct species.

The election, with traverse, is of: a "KIT" with "information" of:

- (A) sodium hexametaphosphate, $n=21$; (as in Examples 3 and 4); the elected polyphosphate
- (B) beverages containing fruit juice; (as in Examples 3 and 4); the elected acidic beverage
- (C) carbohydrate sweeteners, as high fructose corn syrup (Example 3) , or sugar (Example 4); (known to cause "caries");
- (D) substantially free of calcium and fluoride, (both known to reduce tooth erosion in acidic beverages) as required by the claims as presently amended.

The Examiner regards claim-encompassed polyphosphates and elected sodium hexametaphosphate ($n=21$) as well-known commercially available source anticaries compounds to yield phosphate ion in water, and the tooth erosion benefit of the sodium phosphate salt

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monosodium dihydrogen phosphate, "MDP", NaH_2PO_4 discovered by McDonald et al and Muhler to reduce tooth erosion in such acidic beverages, to be due to the expected release of phosphate ion upon aqueous dissolution of the phosphate salt.

Whether or not the selection of sodium hexametaphosphate polyphosphate would be immediately envisioned for the same tooth erosion benefit, or whether or not one skilled in the art would have motivation to substitute sodium hexametaphosphate or other encompassed species of polyphosphates for the tooth erosion benefitting monosodium dihydrogen phosphate, based on expert knowledge that both are well known sources of phosphate ion requires a Rule 132 Declaration of an expert (i.e. by applicants or colleagues). Counsel's remarks are respected but are not considered herein to be an expert's opinion.

The undersigned USPTO Examiner has consulted with sector practice specialists and, sector mentors, on the proposed "information" basis for patenting orange juice with hexametaphosphate by the very interesting legal argust as a "KIT" (information on dental erosion) See: In re Haller, 73 USPQ 403, (holding patentable novelty cannot be imparted by printed matter) based upon In re Miller, 164 USPQ 46, and In re Gerlick, 217 USPQ 401, and has been advised, in the interim, that the policy of this sector, is to distinguish both cases as reacting functional structural elements claimed, more that "information", etc. "KITS" of old compositions whose patentable novelty depends on printed information on a new use are involved.

Prior to setting forth the Office Action, for clarity of prosecution, the following is noted about printed matter:

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The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned... In accordance with the patent statutes, and article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; with out the printed indicia or numbers, the

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substrates lose their function. Such is not the case with the instantly claimed articles. The “KITS”, claimed articles remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in ^{the} instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a).

Thus the instructions for use included in a kit or article manufacture constitute an “intended use” for that kit or article of manufacture.

Intended use does not impart patentable weight to a product. See MPEP 211.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the claims are drawn to “KITS” of an old composition article of manufacture which further comprises “information” labeling instructions. The intended use which is recited on the label or package “information” lacks ^{it} of function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, ^{it} ~~the~~ can still be used by the skilled artisan for other purposes. Therefore the “KIT” old article or composition which are comprised within the article of

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manufacture are unpatentable over the prior art because they function equally effectively with or without the labeling and accordingly no functional relationship exists between the instructions for use and the composition and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition "KIT" with a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102, and 103 rejections.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 to 15, 17 to 20 and 22 to "KITS" are rejected under 35 U.S.C. 102(b) as being anticipated or under 35 USC 103 as obvious, for the "information" provided by each of condensed phosphate or polyphosphate salt supplemented low pH beverages of the U.S. patents cited on the PTO-892, namely, the commonly assigned Proctor & Gamble patents to:

Calderas (sodium hexametaphosphate, same as elected herein), Smith et al., Montezinos (I-II), Ekanayake et al. (same), McKenna et al., Tung et al. , Cirigliano et al. (I-II), Sokolik et al. , and Zablocki et al. each describing encompassed species of acidic beverages having a pH less than about 5, containing sodium hexametaphosphate, (same as elected herein), or other encompassed species of sodium or potassium, condensed phosphate or polyphosphate salts, Calderas, for example employing 900 to 3000 parts per million polyphosphate with sodium hexametaphosphate, same as applicant elected herein in Examples 1-4), as the encompassed polyphosphate, in a non-carbonated acidic beverage having a pH of between 2.5 and 4.5, as see column 4 lines 7-32 in fruit juices at column 7 lines 39-68, as elected and tea at column 8 lines 12-28, with encompassed species of sweeteners at column 8 lines 30-68, also avoiding calcium as well as iron and magnesium fortification since these polyvalent cations combine to and inactivate the polyphosphate component of the non-carbonated beverages, as see column 9 lines 27-30, and differing ~~from~~ ^{from} these "KIT" claims in not providing information that use of the beverage provides the inherent dental erosion advantage, benefit, or property.

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Smith et al. (Proctor & Gamble), similar to Calderas (Proctor & Gamble), include 300 ppm to 3000 ppm of an encompassed polyphosphate having an average chain length of about 17 to about 60 to, an encompassed species of a non-carbonated beverage having a pH of between 2.5 and 4.5, differing from these "KIT" claims in not providing the information feature.

The prior art polyphosphate supplemented acid beverages do not become patentable "KITS" by being labeled with associated information to the effect that since polyphosphates may prevent tooth erosion, or caries, as see Harris et al (1967) McGaughey et al (1977) and Shibata et al. (1982), that they may reduce their tooth erosion potential of the acid low pH beverages, a property described for ~~then~~^{them} by Lussi et al., (1995).

Applicant's attention is directed to a recent legal decision, binding on USPTO patent examiners, on a vital issue of "new use" of known compositions, attempts to repatent them as products.

Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir.-1999), holds that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not precluding a finding of anticipation. Whether or not an element is inherent in the prior art, is a fact question. Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new to the discoverer. The fact that the prior art taught away from the claim is, in fact, only "a

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showing that the prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency. The "KITS" are not patentably distinct by virtue of (B) information, as noted above. The subjects described by each of Harris et al McGaughey et al and Shibata et al proved the anticaries benefit of sodium hexametaphosphate in their diet and could be provided with this information. The claims do not require that the user can be taught to understand the information.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 to 15, 17 to 20 and 22 to "KITS" are rejected under 35 U.S.C. 103(a) as being unpatentable over the foregoing sodium hexametaphosphate added acidic pH fruit juice beverages described by each of the foregoing: Calderas, Smith et al, Motezinos (I-II), Ekanayake et al, McKenna et al, Tung et al, Ciriglione et al (I-II), Soklik et al, and Zablocki et al (details as noted

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above) none of which describe the information component or even the reduction of tooth erosion benefit imparted to the acidic pH fruit juice benefit by virtue of the sodium hexametaphosphate, taken in further view of Shibata et al (1982) or McGaughey et al (1977) or Harris et al (1967) and each of Muhler (1970) (as abstracted) and McDonald et al. (1973) (Details as noted above), each anticipating the addition of a sodium or potassium phosphate salts to such a low pH acid beverage to reduce their tooth eroding potential with such potassium polyphosphates or condensed phosphate salts as well as the selection of encompassed low pH acid beverage species, to practice this would be prima facie obvious as an apt source for phosphate ion, if not immediately envisioned, In re Schaumann et al ., 197 USPQ 5. The feature of kit claims of including information that the use of the beverage provides treatment against dental erosion is not patentable thereover, (In re Haller, 73 USPQ 403, CCPA-1947) since it is predicated on printed matter on or “associated with” (advertising in the media) the otherwise old beverage or its package.

Applicant has presented “KIT” claims, drawn to no more than the old polyphosphate described in a known acidic beverage, one potentially possibly causing caries, or dental erosion by its oral administration, and claims to “KITS” (no more than label or media information), of such admittedly known species of acidic beverages having a pH of less than 5, which admittedly are considered to directly erode dental enamel, admittedly, according to Lussi et al. (1995), Caries Research Volume 29 pages 349-354; it being admitted prior art that the encompassed species of acidic low pH dental eroding beverages include : fruit juice, as elected, carbonated cola and other

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soft drinks; as well as tea; milk and milk based beverages; (containing fluoride and calcium, respectively), it being admitted prior art only that fluoride and/or calcium but not polyphosphates can expectedly lessen dental erosion, the improvement to such dental eroding ingestible acid low pH beverages free of calcium and fluoride being that "information" is provided with the beverage contains sodium or potassium polyphosphate salts "treats dental erosion". This is "new use" of a known beverage, another reason to market it. Is this patentable? Is there motivation to do so?

The novelty of kit claims over inadvertently overlooked not admitted above note cited and applied prior art acidic beverages containing the sodium or potassium species of encompassed polyphosphates (included described or taught for reasons other than to treat dental erosion) (cited as known on the PTO-892 attached), (clearly meeting Part (a) of claim 1), is found in Part (b) of "KIT", "INFORMATION THAT THE USE OF THE BEVERAGE COMPOSITION PROVIDING TREATMENT AGAINST DENTAL EROSION". The CCPA in 1947 in In re Haller, 73 USPQ 403 , held that novelty cannot be predicated on printed instructions (or on a label to reconstitute or to dilute a known composition with water to use it as an insecticidal spray). This Court case, never overturned, is binding as a precedent and Federal Circuit precedents are binding on USPTO examiners. The Miller and Gulak decisions can be distinguished on their facts, they involve functional elements claimed in Miller, a ratio indicating legend and volumetric indicia on a measuring receptacle in Gulak the printed material was novel and non-obvious both cases are prior to the recent Atlas case, (cited above).

A review of the applicant cited admitted prior art cited on the PTO-1449 IDS includes:

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Lussi et al. (1995) (as noted above) identifying the species of low pH tooth erosive acid beverages encompassed by these claims to include orange juice and other citrus and fruit juices, apple juice, Sprite, Coca cola, Lemon Lime and other carbonated soft drinks, Sweppes, sports drinks, wine and beer, to which fluoride had been added to minimize (but not totally prevent) tooth erosion, differing from these "KITS" in having no polyphosphate content and no "information" component.

Ruessner et al (1975), describe and anticipate the addition, to encompass species of acidic beverages, namely encompassed pH range canned and frozen orange juice, and carbonated lemon lime beverages, of encompassed percentages of phosphates, namely (page 366, column 1, Table I), 0.15% sodium trimetaphosphate; an encompassed polyphosphate species 0.21% monosodium orthophosphate (NaH_2PO_4); with or without 0.08% monofluorophosphate, or 0.15% calcium chloride, the levels of the phosphate compound selected to yield 0.5 mg of phosphorus per ml, and 0.5 mg per ml of calcium. It is presumed that the researchers, being literate, provided labels, with information, to guide the trials. A control group had no calcium or polyphosphates in encompassed concentrations, with and without sucrose and/or glucose, as providing anti-caries activity, as tested at 2% phosphate level and high sugar diet (in hamsters) in the absence of fluoride, in Shibata et al. It is presumed that the hamsters (users) could not read or understand any labeled information provided.

Examiner cited Muhler (1970) South Africa 6904743, and McDonald et al. (1973), both cited on the PTO-892 teach and describe the feature of adding a sodium phosphate salt-

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monosodium dihydrogen phosphate to impart phosphate ion ~~sto~~ acid pH beverages to reduce tooth erosion, same as herein. The feature of selecting polyphosphate as phosphate sources would be prima facie obvious, if not in fact "immediately envisioned" species under In re Schaumann et al ., 197 USPQ 5.

Shibata et al. (1982), McGaughey et al. (1977) and Harris et al (1967) all, (cited by applicant) each motivates the inclusion in the diet or drinking water beverage of encompassed species of these antacids condensed phosphates of polyphosphates, but are silent on any "information" provided to guide the researchers.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 11 to 15, 17 to 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of each of: Shibata et al (1982); MC Gaughey et al (1977) or Harris et al (1967) each teaching the anticaries advantage benefit or property of sodium hexametaphosphate (as elected) and the other claim encompassed polyphosphate species, taken with anyone of each of: Lussi et al (1995); Ruessner et al (1975); McDonald et al (1973); or Muhler (1970), each describing the tendency of such acidic and sugar sweetened beverages, having a pH ^{of} ~~to~~ less than about 5, “substantially free” ^{of} ~~to~~ calcium and fluoride, to cause caries, to cause dental erosion. The primary references clearly motivate the inclusion of anticaries tooth protective amounts of sodium hexametaphosphate ~~And~~ analogous encompassed species of polyphosphate into such tooth ~~eroding~~ acidic beverages, whose sugar sweetener can also cause caries. It is obvious to market the combination with media and label information, provided to inform the user of a reduced cariogenic tendency to cause dental evosion, as claimed in these “KITS”..

From the teaching of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shep Rose

Shep Rose
Senior Primary Examiner
Art unit 1614

SKR:LR
November 20, 2001

**SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200**